

REMARKS

With entry of this amendment, the status of the claims is as follows:

Original: 3-6, 10, 12-16 and 18-20

Currently amended: 20

Previously presented: 1, 2, 7-9, 11 and 17

Canceled: 19 and 21-22

New: None

With entry of this amendment, claims 1-18 and 20 are pending. Reconsideration is requested.

Claim 19 has been canceled. Claims 21 and 22 were canceled in a previous amendment.

Claim 20 has been amended to delete the references to "preventing" and to refer to "HIV-1".

Information Disclosure Statement

An information disclosure statement (IDS) accompanies this amendment. The information disclosure statement lists US2006/0024330 which corresponds to co-pending USSN 10/526275 which has the same effective filing date as the subject application. The IDS also lists the amendment with the current claims in co-pending USSN 10/526275. The IDS also lists the references cited in the remarks below pertaining to the section 112 rejection.

Rejection under 35 U.S.C. § 112

Claims 19 and 20 have been rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. The Examiner has asserted that while the specification is enabling for a method of treating infection due to HIV-1, it is not enabling for inhibiting HIV integrase generally, or for preventing or treating infection by HIV generally, or for preventing, treating or delaying the onset of AIDS in a subject. While not conceding the correctness of the Examiner's position, claim 19 has been canceled rendering the rejection moot as applied thereto and claim 20 has been amended to refer to HIV-1 and to remove the references to preventing. Applicants reserve the right to pursue the deleted subject matter in one or more continuing applications.

To the extent the rejection of claim 20 applies to treating or delaying the onset of AIDS due to HIV-1, it is traversed. As stated in the application (page 1, lines 30-34), the integrase enzyme is essential to the replication of HIV. The application further discloses (page 1, lines 17-20) that HIV infection is the cause of AIDS. It was known prior to the filing of this application that infection by HIV can result in the progressive destruction of the immune system, specifically the depletion of CD4-positive T lymphocytes, eventually resulting in AIDS (see,

e.g., Mylonakis et al., *American Family Physician* 2001, 63, 483-490 – note especially Figure 1 on p. 484) (copy enclosed with the accompanying IDS). It was also known that (i) there is a correlation between viral load and the progression of AIDS, wherein HIV-infected individuals with high viral loads are more likely to progress to AIDS, and that (ii) treatment of infected individuals with antiretroviral therapy can reduce viral load and thereby delay progression to AIDS and can also effectively treat individuals who had progressed to AIDS (see, e.g., Schooley, *AIDS* 1995, 9 (suppl 2): S15-S19; Moyle et al., *Drugs* 1998, 55, 383-404; Hammer, *AIDS* 1996, 10 (suppl 3), S1-S11 (copies of the foregoing references are enclosed with the accompanying IDS)). Accordingly, in view of the teachings in the instant specification in combination with the known art, the skilled artisan at the time the subject application was filed would expect the claimed integrase inhibitors to limit or reduce the HIV viral load and thereby delay the onset of AIDS and result in the treatment of AIDS. The fact that AIDS can manifest itself as any one or more of a number of diseases or disorders is of no import, because the underlying cause of these conditions is the HIV viral load. When the viral load is reduced and brought under control, these conditions would be expected to lessen in severity and/or disappear. The specification is therefore enabling for treating and delaying the onset of AIDS due to HIV-1.

In view of the foregoing remarks and amendment, withdrawal of the rejection of claim 20 is requested.

The application is believed to be in condition for allowance and passage to issue is requested. The Examiner is invited to telephone the undersigned should any minor matters need to be resolved before a Notice of Allowance can be mailed.

Respectfully submitted,

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